

### Remarks

Claims 1-40 were pending in this application. Claims 19, 26, and 40 have been amended, claims 1-18 have been canceled herein without prejudice, and no claims have been added.

Applicants wish to thank the Examiner for extending the courtesy of a telephone interview on March 24, 2006 during which the Lee reference was discussed along with the above claim amendments. Reconsideration of this application is respectfully requested in light of the above amendments and the following remarks.

#### Rejection of Claims 1-40 Under 35 U.S.C. § 112

Claims 1-40 have been rejected under 35 U.S.C. § 112, second paragraph, as being indefinite due to the phrase "absence of a synthetic matrix." Applicants have amended claims 19 and 40 herein to recite "without disposing the cells within an exogenous scaffold material" as discussed with the Examiner, wherein support for this amendment can be found, for example, at p. 4, lines 4-6 of the specification. The Examiner has also objected to the phrase "bone-like" as being indefinite. In response, claim 26 has been amended herein to recite that the anchors include "at least one of hydroxyapatite and calcium phosphate", wherein support for this amendment can be found at p. 10, lines 12-13 of the specification. Accordingly, Applicants respectfully request reconsideration and withdrawal of the rejection of claims under 35 U.S.C. § 112.

#### Double Patenting Rejection of Claims 1-18

Claims 1-18 have been rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 1 of U.S. Patent No. 6,777,234. Claims 1-18 have been canceled herein without prejudice, such that this rejection is now obviated. Applicants reserve the right to pursue these claims in a continuation application.

**Rejection of Claims Under 35 U.S.C. § 102(b) Over Lee**

Claims 1-5, 14-15, 18-19, 23, 26, 33, 35-36, and 38-40 have been rejected under 35 U.S.C. § 102(b) as being anticipated by U.S. Patent No. 5,756,350 issued to Lee et al. ("Lee"). As described above, independent claims 19 and 40 now recite that cells are provided on the substrate "without disposing the cells within an exogenous scaffold material." As discussed during the telephone interview, this is in direct contrast to Lee, wherein it is described that "[t]he first step in the formation of an oriented tissue-equivalent comprises forming a collagen gel having connective tissue cells dispersed therein" (*see* Lee, col. 4, lines 48-50). Therefore, claims 19 and 40 are patentably distinguishable over Lee, and reconsideration and withdrawal of the rejection of these claims, along with their corresponding dependent claims, is respectfully requested.

**Rejection of Claims Under 35 U.S.C. § 103(a) Over Lee**

Claims 1-40 have been rejected under 35 U.S.C. § 103(a) as being unpatentable over Lee. For the reasons described above, Lee does not disclose or suggest "fibroblast cells provided on the substrate without disposing the cells within an exogenous scaffold material" as recited in independent claims 19 and 40. Accordingly, Applicant respectfully requests reconsideration and withdrawal of the rejection of claims under 35 U.S.C. § 103(a).

Conclusion

In summary, Applicants believe that the claims now meet all formal and substantive requirements and that the case is in appropriate condition for allowance. Accordingly, such action is respectfully requested. If a telephone conference would expedite allowance of the case or resolve any further questions, such a call is invited at the Examiner's convenience.

Please charge the Petition fee of \$60.00 and any additional fees or credit any overpayments as a result of the filing of this paper to our Deposit Account No. 02-3978.

Respectfully submitted,  
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